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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,884	06/05/2007	Edith Mathiowitz	BU 1594	3510
23579	7590	01/14/2011	EXAMINER	
Pabst Patent Group LLP 1545 PEACHTREE STREET NE SUITE 320 ATLANTA, GA 30309			KIM, TAEYOON	
			ART UNIT	PAPER NUMBER
			1651	
			MAIL DATE	DELIVERY MODE
			01/14/2011	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/587,884	MATHIOWITZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Taeyoon Kim	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44,46-51,55-61 and 65-74 is/are pending in the application.
- 4a) Of the above claim(s) 44,46-51,58-61,65 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-57 and 67-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment and response filed on 11/24/2010 has been received and entered into the case.

Claims 1-43, 52-54 and 62-64 are cancelled, and claims 68-74 are newly added. Claims 44, 46-51, 58-61, 65 and 66 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 55-57 and 67-74 have been considered on the merits. All arguments have been fully considered.

#### **Claim Rejections - 35 USC § 103**

The claim rejection under 35 U.S.C. § 103 has been withdrawn due to the amendment.

#### **Claim Rejections - 35 USC § 112 (New Rejection)**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 recites the limitation "the angiogenic/vasculogenic factors" or "the bone marrow recruiting factors" in line 1 or 5-6, respectively. There is insufficient antecedent basis for this limitation in the claim. The instant claim is dependent on claim 55, and claim 55 does not disclose these limitations.

Claims 55-57 and 67-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a prima facie case.

The instant claims are interpreted as an implant comprising an external porous housing comprising nylon (nylon pouch/mesh) and a plurality of particles having a diameter of 10 nm to 10  $\mu$ m, wherein the particles comprise one or more cytokines and bone marrow recruiting factors.

The structural requirement of the nylon pouch is that the pore size of the pouch should be sufficiently large enough to allow movement of the progenitor cells into the implant.

It is understood that the particles for controlled release of the cytokines and/or bone marrow recruiting factors are inside the pouch, and the claimed implant is directed particles (drug delivery system) being inserted in the pouch.

The diameter of the claimed particles is ranging from 10 nm to 10  $\mu$ m according to the current amendment.

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Considering the pore size of the pouch requiring sufficiently large to allow free movement of the cells, for example 15-20  $\mu\text{m}$  as disclosed in the Example of the specification (p.35), the instant amendment to the range of particle size raises an issue that the particles of the claimed size (i.e. 10 nm-10  $\mu\text{m}$ ) would not be held or retained within the pouch. Rather a person of ordinary skill in the art would recognize that the particles would leak or escape through the pores larger than the diameter of the particles.

Since the structural relationship between the external housing (pouch/mesh) and the particles is understood such that the particles should be housed or retained in the external pouch/mesh. That is the pouch should be able to retain or trap the particles inside of the pouch, and at the same time the pore of the pouch should be large enough to allow the cells entering the pouch. A person of ordinary skill in the art would consider that unless the size of the particles is larger than the pore size of the pouch/mesh, the particles of smaller size would be released from the external housing.

However, the currently claimed range is significantly smaller than the size of the pores of the nylon mesh or pouch (e.g. 15-20  $\mu\text{m}$ ), and therefore, it is considered that a person of ordinary skill in the art would not be enabled to make the claimed implant having an external housing with particles of 10 nm - 10  $\mu\text{m}$  of diameter.

### **Conclusion**

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/  
Primary Examiner, Art Unit 1651